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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/088,805      | 03/21/2002  | Geert Verreck        | JANS-0031           | 2459             |

7590 12/16/2005  
Philip S Johnson  
Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003

EXAMINER

VU, JAKE MINH

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1618

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/088,805 | <b>Applicant(s)</b><br>VERRECK ET AL. |  |
|                              | <b>Examiner</b><br>Jake M. Vu        | <b>Art Unit</b><br>1618               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12, 13 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 13, and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>05/27/05, 11/22/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt is acknowledged of Applicants' **Request for Continued Examination** filed on 11/22/04 and the Information Disclosure Statements filed on 05/27/05 and 11/22/04. Claims 1-10, 12, 13, and 28 are pending in the instant application.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 2-4, 7, 12, and 13 recite the limitation "A particle according to claim 1, 25, or 26..." There is insufficient antecedent basis for this limitation in the claim, because claims 25 and 25 have been cancelled previously.

### ***Double Patenting***

Applicants' previously argued "both *Andries* patent and the subject application were commonly owned by Johnson & Johnson at the time the subject invention was made. Accordingly, *Andries* is not available as prior art in accordance with 35 U.S.C. § 103(c)". In this case, a nonstatutory double patenting rejection would be proper.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 12, 13, and 28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Andries et al (US 6,197,779) in view of Baert et al (EP 0872233).

Applicants' claims are directed to a particle comprising of: a compound of formula I-A, an anti-viral compound; and hydroxypropyl methylcellulose. Wherein, the particle has a size of less than 1500um; in non-crystalline phase; two parts said compound and three parts hydroxypropyl methylcellulose; and in solid solution to form a solid dispersion.

Andries disclosed the particle compound of formula I-A, an anti-viral compound. However, Andries does not teach adding hydroxypropyl methylcellulose. Wherein, the particle has a size of less than 1500um; in non-crystalline phase; two parts said compound and three parts hydroxypropyl methylcellulose; and in solid solution to form a solid dispersion.

Baert teaches an anti-viral composition comprised of: an antiviral compound (abstract; col. 10, line 18-19); and hydroxypropyl methylcellulose (pg. 4, line 17). Wherein, the particle has a size of less than 1500um, such as less than 600um (pg. 3, line 53); in non-crystalline phase (pg. 4, line 5); two parts said compound and three parts hydroxypropyl methylcellulose (pg. 4, line 57); and in solid solution to form a solid dispersion (pg. 3, line 1-16). Additionally, the compound can be in amorphous or microcrystalline form (pg. 3, line 12).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate the teaching of Baert with Andries to make an anti-viral composition comprised of formula I-A. The person of ordinary skill in the art would have been motivated to make those modifications, because the modification would have improved bioavailability. The person of ordinary skill in the art would reasonably have

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expected success, because Baert's composition contained an anti-viral compound, in which formula I-A in the instant application is an anti-viral compound.

### ***Telephonic Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571) 272-8148. The examiner can normally be reached on Mon-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jake M. Vu, PharmD, JD  
Art Unit 1618

  
MICHAEL HARTLEY  
PRIMARY EXAMINER